510 (k) Summary
as required by section 807.92(c)

Subscribers Name & Address

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Trade Names

Siemens Predicate device Servo*i* **Ventilator System (K010925)**
Options : Bi-Vent ventilation mode and CO2 analyzer

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Ventilator, Continuous (Respirator)	73 CBK	II	868.5895
Carbon dioxide gas analyser	CCK	II	868.1400

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed		*510(k) #*
Bi- Vent spontaneous mode breathing;		
PB840	Puritan Bennet	K001646
Evita 4	Dräger	K980642
Galileo	Hamilton	K001686
Harmony S/T	Respironics	K984407
KnightStar 330	Nellcor	K003075
CO2 Analyzer;		
Infnity etCO2 pod	Siemens	K003550

Device Description (for detailed description see Section F)

The ventilator is the same as described in the notification K010925. This application if for the following options to the Servo-i ventilator family.

The Bi-Vent mode is a Pressure controlled mode with added possibility to allow unrestricted spontaneous breathing, also at high level pressure.

The CO2 analyzer displays continuous CO2 curves of mainstream expired air and etCO2 figures. The aim is to measure the concentration of carbon dioxide to aid in determining the patient's ventilatory, circulatory, and metabolic status.

Intended Use of the Device:

The indented use is the same as in K010925 (Servo-i application) including the;

- *Bi-Vent mode* a pressure controlled ventilation that allows the patient the opportunity of unrestricted spontaneous breathing.
- *CO2 analyzer* displaying continuous CO2 curves of mainstream expired air to measure the concentration of carbon dioxide to aid in determining the patient's ventilatory, circulatory, and metabolic status.

The indented use is the same as in K010925 application.

Intended Use of the Device:

The Servo-i Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency. Servo-i is a ventilator system to be used only by health care providers in hospitals or health care facilities and for in-hospital transport.
Note: The Servo-i Ventilator System is not intended to be used with any anesthetic agents.

Intended operator:

Servo-i is a ventilator system with advanced functionality. It may be used only by professional health care providers who have sufficient experience in ventilator treatment.

Intended Patient Populations:

Servo-i Infant for patient weight 0.5-30 kg
Servo-i Adult for patient weight 10-250 kg
Servo-i Universal for patient weight 0.5 - 250 kg.

Intended Use Environment:

The Servo^i Ventilator System is designed to be used at the bedside and for in-hospital transport.
The Servo^i Ventilator System is not intended to be used with any anesthetic agents.
The Servo^i Ventilator System is not compatible for use in a MRI magnetic field

Summary of technological characteristics of Device and Predicate Device:

Carbon dioxide analyzer.

The CO2 functionality uses the Servo-i screen for presentation of mainstream CO2 measurements. The airway adapter is placed at the Y-piece and the sensor is snapped on to the airway adapter. The CO2 Analyser module receives signals from the sensor that reflects the variations of CO2 in expiratory gas. This allows for continuously monitoring shown in a waveform indicating the CO2 concentration and numerical presentations of EtCO2 and $\dot{V}CO2$.

The CO2 functionality for the Servo-i CO2 module is equivalent to the CO2 analyzer in Siemens Infinity CO2 pod (file number K003550), an accessory item employed with the Siemens ServoVentilator 300A, which also is technologically based and componentry sourced as Sensor and input electronics card from Novametrix. (file number K963380)

Bi-Vent mode

Bi-Vent is a Biphasic positive airway pressure (BIPAP™) which is equivalent to airway pressure release ventilation (APRV) which has been designed to provide ventilatory support with unrestricted, spontaneous breathing. These modalities operate by periodic switching between two levels of continuous positive airway pressure while allowing spontaneous breathing in any phase of the ventilatory cycle. However, in the absence of spontaneous breathing, airway pressure release ventilation/biphasic positive airway pressure is identical to conventional pressure-limited, time-cycled, mechanical ventilation, eg Pressure Control.

Bi-Vent ventilator mode is used on many ventilators for both critical care and home care. The Bi Vent mode is substantially equivalent to Puritan Bennet 840 ventilator with NeoMode option (K001646), Dräger Evita 4 – (K980642) for adult and with Neo flow for neonates , Savina (Dräger – K003068), Galileo (Hamilton - K001686), and Harmony S/T Respironics - K984407 and KnightStar 330 (Nellcor – K003075)

The technology used is assessed, verification and design validation on animals show that the Servo*i* Ventilator System has the equivalent clinical performance with the above options.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2002

Mr. Richard M. Flynn
Manager, RA/QA
Siemens Medical Solutions USA, Incorporated
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K022132
Trade/Device Name: Servo[i] Ventilator System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 23, 2002
Received: August 27, 2002

Dear Mr. Flynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ***K022132***

Device Name: Servo^i Ventilator System-

Indications For Use:

The Servo^i Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency. Servo^i is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K022132